



## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

**[Docket No. DEA-559]**

#### **Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturers of Marihuana: Royal Emerald Pharmaceuticals Research and Development**

**ACTION:** Notice of application.

**SUMMARY:** The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic classes of controlled substances listed in schedule I. Prior to making decisions on this and other pending applications, DEA intends to promulgate regulations that govern the program of growing marihuana for scientific and medical research under DEA registration.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW 8701 Morrisette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No. DEA-559 in all correspondence, including attachments.

**SUPPLEMENTARY INFORMATION:** The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes

specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If its application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a Bulk Manufacturer of Marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a) as described in 84 FR 44920, published on August 27, 2019.

In accordance with **21 CFR 1301.33(a)**, DEA is providing notice that on September 24, 2019, Royal Emerald Pharmaceuticals Research and Development, 7220 Trade Street, Suite 340, San Diego, California 92121-2324 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

<b>Controlled Substance</b>	<b>Drug Code</b>	<b>Schedule</b>
Marihuana Extract	7350	1
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The applicant noticed above applied to become registered with DEA to grow marihuana as a bulk manufacturer subsequent to a 2016 DEA policy statement that provided information on how it intended to expand the number of registrations, and described in general terms the way it would oversee those additional growers. Before DEA completes the evaluation and registration process for applicants to grow marihuana, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law, as described in 84 FR 44920.

**Dated:** December 6, 2019.

**William T. McDermott,**  
*Assistant Administrator.*

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